IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	Guy E. Horne, Jr., et al.
Application No. 10/766,295	Filing Date: January 27, 2004
Title of Application:	Composite Flexible Endoscope Insertion Shaft With Tubular Substructure
Confirmation No. 9340	Art Unit: 3739
Examiner	Matthew J. Kasztejna

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Appeal Brief Under 37 CFR §41.37

Dear Sir:

Appellants file the present Appeal Brief in conjunction with a Notice of Appeal filed on February 9, 2009 requesting reinstatement of its appeal to the Board in view of the Office Action mailed on November 7, 2008, reopening prosecution after Appellants had filed their previous Appeal Brief. A Claims Appendix is submitted herewith, as are Appendices related to evidence previously submitted and related proceedings to the case.

(i) Real Party In Interest

The real party in interest is Karl Storz Endovision, Inc., 91 Carpenter Hill Road,

Charlton, MA, 01507, assignee of the present patent application.

(ii) Related Appeals and Interferences

On May 28, 2008, Appellants filed a Notice of Appeal to the Board of Patent

Appeals and Interferences in the present application, followed by an Appeal Brief filed on

August 21, 2008. In response to the appeal, the Examiner reopened prosecution and

issued a new non-final Office Action dated November 7, 2008. The Examiner has again

made substantially identical rejections, which are again being appealed herein.

(iii) Status Of Claims

Claims 8-9 and 14-15 have been cancelled. Claims 1-7 and 10-13 stand rejected

and are the subject of the instant Appeal. A copy of each of these claims is attached

hereto in the Claims Appendix.

(iv) Status Of Amendments

There are no pending or unentered Amendments. Appellants have not filed any

Amendments after the mailing of the most recent Office Action on November 7, 2008.

(v) Summary Of Claimed Subject Matter

Claims 1 and 13 are the rejected independent claims and are discussed below.

Independent Claim 1

Claim 1 is directed to an endoscope insertion shaft, which includes a tubular member (102) and a sheath (128). The tubular member (102) has an axis (120) and includes a continuous wall to form a closed interior (see Fig. 4). The continuous wall includes at least one aperture (118) for increasing the flexibility of the tubular member (102) (Page 4, line 14 – Page 5, line 8; Fig. 3). The sheath (128) includes the following layers: a braided layer (106), a laminating layer (108), a wear layer (110), and a barrier layer (104) (Page 6, lines 6-20; Fig. 1). The braided layer (106) jackets the continuous wall of the tubular member (102) (Page 6, lines 6-20). The barrier layer (104) comprises a polyester wrap and is disposed between the continuous wall of the tubular member (102) and the braided layer (106) of the sheath (128) (Page 6, lines 6-20; Fig. 1). The barrier layer (104) jackets the tubular member (102) to form a seal along the length of the tubular member (102) (Page 6, lines 6-20; Fig. 1).

Thus, the endoscope insertion shaft of claim 1 includes four layers over the tubular member (102), which are disposed in a particular order: the barrier layer (104), the braided layer (106), the laminating layer (108), and the wear layer (110).

Independent Claim 13

Claim 13 is also directed to an endoscope insertion shaft that includes a tubular member having an axis (120) and including a continuous wall to form a closed interior (see Fig. 4). The continuous wall includes at least one aperture (118) for increasing the flexibility of the tubular member (102) (Page 4, line 14 – Page 5, line 8; Fig. 3). A barrier layer (104) jackets the tubular member (102) to form a seal extending along the length of the tubular member (102) around the continuous wall (Page 6, lines 6-20; Fig.

- 1). The barrier layer (102) is jacketed by a braided layer (106) (Page 6, lines 6-20; Fig.
- The endoscope insertion shaft further includes a laminating layer (108) and a wear layer (110) (Page 6, lines 6-20; Fig. 1). At least the barrier layer (102), the braided layer (106), and the laminating layer (108) are formed as a single composite structure.

Thus, the endoscope insertion shaft of claim 13 includes four layers over the tubular member (102), disposed in a particular order: the barrier layer (104), the braided layer (106), the laminating layer (108), and the wear layer (110).

(vi) Grounds Of Rejection To Be Reviewed On Appeal

Claims 1-7 and 10-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,275,152 to Krauter et al. ("Krauter") in view of U.S. Patent No. 6,749,560 to Konstorum et al. ("Konstorum") and further in view of U.S. Patent No. 6,540,669 to Abe et al. ("Abe").

Appellants respectfully submit that the invention of claims 1-7 and 10-13 would not have been obvious to a person of ordinary skill in the art at the time the invention was made. The Examiner has rejected claims 1-7 and 10-13 under 35 U.S.C. § 103(a) over Krauter et al. in view of Konstorum et al. and Abe et al. The invention of claims 1-7 and 10-13 is neither anticipated nor obvious over the cited references.

Rejection of Independent Claims 1 and 13 under 35 U.S.C. 103(a)

As discussed above, the present invention is directed to an endoscope insertion shaft comprising a tubular member including a continuous wall and including at least one aperture for increasing the flexibility thereof. The tubular member is sheathed or jacketed by <u>four distinct layers</u> in a particular order: a barrier layer jacketing the tubular member, a braided layer jacketing the barrier layer, a laminating layer, and a wear layer.

Krauter et al. disclose an insertion tube body for an endoscope. The tube body 15 includes a helical monocoil 21 extending along a length of the tube body (Col. 3, lines 40-41). As shown in FIG. 2 of Krauter et al., a tubular sleeve or jacket 22 of urethane is disposed over the monocoil 21, and a tubular braid layer 23 is disposed over the jacket 22 (Col. 3, lines 43-45). Additionally, a coating 24 of polyurethane impregnates and adheres to the braid 23 and to the jacket 22 and forms an outer skin for the insertion tube body 15 (Col. 3, lines 46-49: Fig. 2). Thus, Krauter et al. clearly

Abe et al. disclose a flexible tube for an endoscope having a core body 2 and an outer cover 3 (Col. 4, lines 52-54). The core body 2 includes a helical coil 21 formed from a flat metal band and a reticular tube 22 formed of braided metal or nonmetal fine wires (Col. 4, line 58 – Col. 5, line 14). The outer cover 3 covers the outer periphery of the core body 2 (Col. 4 lines 52-54). In one embodiment, the outer cover 3 comprises a laminated structure that includes an inner layer 32, an intermediate layer 33, and an outer layer 34 (Col. 10, lines 39-42). Thus, Abe et al. disclose an outer cover having three layers that jacket a braided layer (reticular tube 22). While Abe et al. disclose four layers jacketing the helical coil 21, Abe et al. teach that these layers are disposed in a particular order that differs significantly from the order of the layers in claims 1 and 13. Abe et al. specifically teach that all of the layers of the outer cover 3 jacket the braided reticular tube 22. Thus, Abe et al. fail to disclose a barrier layer between the braided layer and the helical coil 21, as recited in claims 1 and 13 of the present application.

Abe et al. also contain specific teachings relating to the functions of the outer layer and its constituent parts. Abe et al. teach that the inner layer 32 is formed of a material that adheres well with a coating 231 that is deposited on parts of the reticular

tube 22 (Col. 11, lines 1-4). Coating 231 is deposited over at least one of the fine wires 23 for the purpose of forming a strong bond between the reticular tube 22 and the outer cover 3 (Col. 5, lines 21-35). This is achieved by facilitating the inner layer 32 of the cover 3 to flow through openings in the braided layer 22, to contact the coil 21, and to create protrusions 31 that extend into the gaps 25 of the coil 21. The material of the inner layer 32 is also selected to be suitable for forming protruding portions 31, which serve to anchor the outer cover 3 to the core body 2 (Col. 7, lines 25-44). FIG. 5 provides a helpful view of this aspect of the device of Abe et al.

Konstorum et al. disclose an endoscope shaft that includes a slotted tube. The slotted tube is made of a superelastic alloy and has slots formed along one or more sections of the tube's length (Col. 1, lines 19-34). The slots in the tube are arranged to increase the flexibility of the tube (Col. 1, lines 47-48). The endoscope shaft also includes a cover 32 comprised of a resilient plastic or polymer material (Col. 5, lines 7-8). The cover 32 is directly attached to the tube 40 (Col. 5, lines 14-15). Konstorum et al. only disclose use of only one layer over the tubular member (tube 40), and thus clearly fail to disclose or teach the four layers required by the present invention.

Accordingly, Appellants respectfully submit that none of the cited references disclose an endoscope insertion shaft that includes <u>four layers over a tubular member</u> disposed in the particular order recited by all claims of the present application.

The Examiner further argues that although Krauter et al. teach an outer wear layer 24, it is silent with respect to a laminating layer disposed between the wear layer and the braided layer, and that it would have been obvious for one of ordinary skill in the art to include an additional laminated layer between the wear layer and the braided layer in apparatus of Krauter et al. to control resilience and durability of the flexible tube as taught by Abe (Office Action of November 7, 2008, pages 4-5). Appellants respectfully disagree. First, Appellants point out that this assertion is contrary to the Examiner's previous position that "Krauter et al. fails to teach an outermost wear layer in the sheath," as discussed on page 3 of Office Action of February 28, 2008.

Second, Appellants submit that Abe et al. fail to disclose or teach a laminating layer, as recited in the present application. As discussed above, Abe et al. disclose the outer cover 3 disposed over the core body 2. The outer cover 3 comprises the inner layer 32, the intermediate layer 33, and the outer layer 34 (Col. 10, lines 39-42). Abe et al. specifically teach that the inner layer 32 flows through openings in the braided layer 22, contacts the coil 21, and creates protrusions 31 that extend into the gaps 25 of the coil 21 (FIG. 5). Accordingly, the inner layer 32 taught by Abe et al. does not just jacket the braided layer 22, but also extends through the braided layer into the coil 21 (tubular member) and even past the coil 21 through the gaps. In contrast, claims 1 and 13 of the present application recite the tubular member jacketed by four layers_disposed in the particular order: the barrier layer jacketing the tubular member, the braided layer

jacketing the barrier layer, the laminating layer over the braided layer, and the wear layer. The laminating layer of the present invention does not and cannot extend past the braided layer into the tubular member because the tubular member is shielded by the barrier layer. Accordingly, it is clear that the inner layer 32 of Abe et al. is incapable of functioning as the laminating layer of the present invention.

Additionally, Appellants respectfully submit that one of ordinary skill in the art would never have been motivated to include the inner layer 32 of Abe et al. on the device of Krauter et al. because the inner layer of Abe et al. would not work with the layer arrangement taught by Krauter et al. in the way intended by the express teaching of Abe et al. As clearly shown in Fig. 2, Abe et al. expressly teach that the inner layer 32 includes protrusions 31 that protrude into the concave portions in the braided layer 22, reach the outer periphery of the coil 21, and extend into the gaps 25 in the coil 21 (Col. 7, lines 25-37). In contrast, the endoscope disclosed in Krauter et al. includes a jacket 22 between the monocoil 21 and the braid layer 23 (Col. 3, lines 43-46). This jacket 22 acts as a shield between the monocoil and the braid layer, and would prevent any protrusions formed by the inner layer as disclosed in Abe et al. from reaching through the braid layer and into the gaps in the monocoil. Such result would clearly be contrary to the express teaching of Abe et al. One of ordinary skill in the art would have recognized that the inner layer of Abe et al. would not have worked with the later

arrangement of Krauter et al., and thus would not have been motivated to include such inner layer on that basis.

It is the Examiner's burden to establish *prima facie* obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). Obviousness requires a suggestion of all the elements in a claim (*CFMT*, *Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). In the present case, the Examiner's reasoning concerning what would have prompted the skilled worker to have arranged the elements taught in the prior art in the manner necessary to reach the claimed invention is critically flawed because none of the cited references, alone or in combination, disclose all elements of the present invention, and because the express teaching of Abe et al. would have led one of ordinary skill in the art away from including the inner layer disclosed therein on the device of Krauter. As such, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

For at least the foregoing reasons, Appellants respectfully submit that the claimed endoscope insertion shaft is not obvious in light of the cited references and is patentable. One of ordinary skill in the art would never have been motivated to make the combination submitted by the Examiner.

Rejection of Dependent Claims 2-7 and 10-12 under 35 U.S.C. 103(a)

Dependent Claims 2-7 and 10-12 all depend on independent Claim 1, and therefore include all of the limitations of Claim 1, Accordingly, dependent Claims 2-7 and 10-12 are likewise patentable over Krauter et al. in view of Konstorum et al. and Abe et al. for the reasons argued with respect to Claim 1.

Conclusion

For all of the foregoing reasons, it is submitted that the claimed invention is patentable over the cited art. Accordingly, it is submitted that the prior art rejections of Claims 1-7 and 10-13 should be reversed

Respectfully submitted.

/Wesley W. Whitmyer, Jr./

April 1, 2009

Wesley W. Whitmyer, Jr., Registration No. 33,558 Todd M. Oberdick, Registration No. 44,268 Attorneys for Appellant ST.ONGE STEWARD JOHNSTON & REENS LLC 986 Bedford Street Stamford, CT 06905-5619 203 324-6155 Attorneys for Appellant

Claims Appendix to Appeal Brief Under 37 CFR §41.37 Serial No. 10/766.295

An endoscope insertion shaft comprising:

a tubular member including a continuous wall to form a closed interior, said tubular member having an axis and said continuous wall including at least one aperture for increasing the flexibility thereof; and

a sheath comprising at least the following layers:

a braided layer;

a laminating layer:

a wear layer;

wherein the braided layer jackets the continuous wall of said tubular member; and

a barrier layer comprising a polyester wrap is disposed between the continuous wall of said tubular member and the braided layer and jackets the tubular member to form a seal therebetween along the length of the tubular member.

- The endoscope insertion shaft as set forth in Claim 1 wherein the at least one aperture comprises a pattern of apertures.
- The endoscope insertion shaft as set forth in Claim 2 wherein the pattern of apertures comprises a first set of apertures positioned along a line parallel to the axis of the tubular member.
- 4. The endoscope insertion shaft as set forth in Claim 3 wherein the first set of apertures comprises at least one elongated aperture having an axis oriented at an angle to the axis of the tubular member.
- The endoscope insertion shaft as set forth in Claim 4 wherein the angle is in the range from zero to ninety degrees.

- The endoscope insertion shaft as set forth in Claim 2 wherein the pattern of apertures comprises a pair of apertures.
- 7. The endoscope insertion shaft as set forth in Claim 2 wherein the apertures are circumferentially positioned on the tubular member.
- The endoscope as set forth in Claim 1 wherein the laminating layer jackets the braided layer.
- The endoscope as set forth in Claim 10 wherein the wear layer jackets the laminating layer.
- 12. The endoscope as set forth in Claim 1 wherein the sheath comprises a composite material.
- 13. An endoscope insertion shaft comprising:
- a tubular member including a continuous wall to form a closed interior, said tubular member having an axis and including at least one aperture for increasing the flexibility thereof;
- a barrier layer jacketing the tubular member to form a seal extending along the length of said tubular member around said continuous wall of said tubular member;
 - a braided layer jacketing the barrier layer;
 - a laminating laver:
 - a wear layer;
- wherein at least said barrier layer, said braided layer and said laminating layer are formed as a single composite structure.

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Evidence Appendix to Appeal Brief Under 37 CFR §41.37 Serial No. 10/766,295

None.

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Related Proceedings Appendix to Appeal Brief Under 37 CFR §41.37 Serial No. 10/766,295

None.